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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,758	10/23/2000	Shukti Chakravarti	CWV-001.01	7408

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EXAMINER
TIZIO, STEVEN C

ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/694,758	Applicant(s) CHAKRAVARTI, SHUKTI	
	Examiner Steven C Tizio	Art Unit 1627	

-- Th MAILING DATE of this communication appears on the cov r sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Please note: *In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is* ***(703) 305-3704****. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this pilot program. If you have any questions or suggestions please contact Jyothnsa Venkat, Ph.D., Supervisory Examiner, at Jyothsna.Venkat@uspto.gov or 703-308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.*

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-2, drawn to the method for identifying genes, classified in class 435, subclass 6 or class 435, subclass DIG 6.

   II. Claim 3, drawn to the method of generating nucleic acid probes, classified in class 435, subclass 6.

   III. Claim 4, drawn to the method of providing kits for detecting the level of expression of genes, classified in class 435, subclass 810.

   IV. Claims 5-7, drawn to the method for determining the phenotype of a cell,

classified in class 435, subclass 366.

V. Claims 8-11, drawn to the kit for assessing a patient's risk of having or developing an inflammatory bowel disease, classified in class 435, subclass 810.

VI. Claim 12, drawn to the method of doing a business for assessing a patient's risk of having or developing an inflammatory bowel disease, classified in class 705, subclass 2 and 3.

VII. Claim 13, drawn to the method for treating a patient who has developed, or is at risk of developing, an inflammatory bowel disease, classified in class 536, subclass 23.1.

VIII. Claims 14-15, drawn to the nucleic acid array, classified in class 436, subclass 518.

IX. Claim 16, drawn to the drug screening assay, classified in class 435 subclass 6.

X. Claim 17, drawn to the method for treating an animal having an inflammatory bowel disease, classified in class 536, subclass 23.1.

XI. Claim 18, drawn to the pharmaceutical preparation, classified in class 424, subclass 78.08.

2. The inventions are distinct, each from the other because of the following reasons:

3. **Groups I-XI** represent separate and distinct inventions. **Groups I-IV, VI-VII, and IX-X** are drawn to different methods and **Groups V, VIII, and XI** are drawn to different products (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will support separate patents.

4. **Groups I-IV, VI-VII, and IX-X** are related to different methods (i.e., e.g., which have different functions, uses, starting materials, and produce different results) and thus represent separate and distinct inventions. The invention of **Group I** relates to the method of identifying genes related to inflammatory bowel disease; the invention of **Group II** relates to the method of generating nucleic acid probes; the invention of **Group III** relates to the method of providing kits for detecting the level of expression of genes; the invention of **Group IV** relates to the method of determining the phenotype of a cell; the invention of **Group VI** relates to a method of doing a business for assessing a

patient's risk of having or developing, an inflammatory bowel disease; the invention of **Group VII** relates to a method for treating a patient who has developed, or is at risk of developing, an inflammatory bowel disease; the invention of **Group IX** relates to a drug screening assay; and the invention of **Group X** relates to the method of treating an animal having an inflammatory bowel disease. The different methods of **Groups I-IV, VI-VII, and IX-X** do not require each other. The results of the methods are different and the method steps are different. Thus restriction between the groups is proper.

5. **Groups V, VIII, and XI** relate to different products (i.e., e.g., which have different chemical compositions, physical properties, biochemical activities, and biochemical uses) and thus represent separate and distinct inventions. The invention of **Group V** relates to a kit for assessing a patient's risk of having or developing an inflammatory bowel disease; **Group VIII** relates to a nucleic acid array; and the invention of **Group XI** relates to a pharmaceutical preparation. The kit of **Group V** is used to detect an inflammatory bowel disease through the use of nucleic acid probes and an immunoassay. The nucleic acid array of **Group VIII** utilizes nucleic acids to bind to inflammatory bowel disease (IBD) genes whereas the pharmaceutical preparation of **Group XI** can be a variety of compounds used to treat an inflammatory bowel disease. **Groups V, VIII, and XI** are drawn to different products, which do not require each other and they are structurally different. Thus restriction between the groups is proper.

6. Inventions of **Group XI** and of **Group X** are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). There are other methods to treat inflammatory bowel disease besides administering a compound described in **Group X**. Compounds can be used to screen for other disease state changes, including morphology changes in the cell (not just gene expression). The pharmaceutical preparation of **Group XI** can be made up of other compounds that act on other phenotypes and disease states of inflammatory bowel disease; not just compounds that act on gene expression.

7. These inventions are distinct for the reasons above and have acquired a separate status in the art because of their recognized divergent subject matter and/or shown by their different classifications. While some of the aforementioned groups are classified under an identical class/sub-class, the corresponding non-patent literature search remains unaffected. Each of the identified groups may require different searches. For example, methods and products groups require different searches. Therefore, restriction for examination purposes as indicated is proper.

Election of Species

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

A) If **Group IV** is elected, applicants are requested to elect a single gene from Table 1 in claim 5.

B) If **Group V** is elected, applicants are requested to elect a single set of five genes from Table 1 in claim 8.

C) If **Group VIII** is elected, applicants are requested to elect a single species of solid support (paper, membranes, filters, chips, pins and glass) in claim 15.

D) If **Group IX** is elected, applicants are requested to elect either the *in vivo* method (administering a test compound to an animal having an inflammatory bowel disease) or the *in vitro* method (cell composition isolated therefrom) in claim 16.

9. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 6-7, 9-14, and 17-18 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

12. Applicant is required to reply to the restriction requirement within 30 days of mailing this action. See MPEP 809.2(a).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Tizio whose telephone number is (703) 305-1903. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PADMASHRI PONNALURI
PRIMARY EXAMINER

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